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P-2040-USP1


# PROVISIONAL APPLICATION FOR PATENT COVER SHEET (Large Entity)

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)/APPLICANT(S)				
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)		
Israel	Sarussi	Moshav, Ganei Tal, Mobile Mail Hof Aza 79792, ISRAEL		
<input type="checkbox"/> Additional inventors are being named on page 2 attached hereto				
TITLE OF THE INVENTION (280 characters max)				
A SENSOR FOR RADIANCE BASED DIAGNOSTICS				
CORRESPONDENCE ADDRESS				
Direct all correspondence to:				
<input checked="" type="checkbox"/> Customer Number	021884	<div>Place Customer Number Bar Code Label here</div>		
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ENCLOSED APPLICATION PARTS (check all that apply)				
<input checked="" type="checkbox"/> Specification	Number of Pages	13		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	3	<input type="checkbox"/> Other (specify)	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)				
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<input checked="" type="checkbox"/> No.				
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are				

Respectfully submitted,

SIGNATURE



DATE 28 December 1998

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## A SENSOR FOR RADIANCE BASED DIAGNOSTICS

Israel SARUSSI

### FIELD OF THE INVENTION

5           The present invention relates to a sensor and system for radiance based diagnostics of body tissues and to a method for radiance based diagnostics of body tissues.

### BACKGROUND OF THE INVENTION

10           Radiance based diagnostics of body tissues involves radiating a body tissue and obtaining data relating to the transmittance or reflection of the radiated light from the tissue, for analysis of tissue constituents. For example, electro-optical measurement of blood characteristics has been found to be useful in many areas of blood constituent diagnostics, such as glucose levels, oxygen saturation, hematocrit, bilirubin and others. Pulse oximetry is a method  
15           for measuring oxygen saturation in the blood, in which two or more wavelengths are radiated through an organ at a point where blood perfuses the organ. Reflective pulse oximetry employs at least one light source and a least one detector which are placed at the same side of an organ. The light source is for radiating the organ and the detector is for receiving the light reflected from the  
20           organ. The reflected light is analyzed for measuring the percent of saturated oxygen in the blood.

          These methods of body tissue diagnostics usually employ sensors, which are placed on body tissues, and which comprise at least one radiance source for radiating the tissue and at least one radiance detector, for detecting

the rays transmitted through or reflected from the tissue. The accuracy of the results obtained in these methods depends, to a great extent, on ensuring that the detector, or detectors, are exposed only to rays which have passed through the examined tissue and not to other rays, such as rays coming directly from the radiance source.

When a sensor is placed on body tissues, especially on stretched tissues (such as over a bone), or due to irregular tissue surface (such as in wrinkles), there might be a small space between the face of the sensor and the tissue, through which some of the rays can pass directly from the radiance source to the detector, thereby adversely affecting the measurement.

Reference is now made to Fig. 1 which is a schematic side view illustration of a prior art sensor. The sensor, generally referenced 10, contains a light source 12 and a light detector 14. The sensor is placed onto examined tissue 16 and, when operated, light is radiated from light source 12 onto tissue 16. Depending on how the light source 12 is directed, most of the light will pass through the tissue 16 and be partly reflected from the tissue. The reflected light 14' will be received by detector 14 to be analyzed. However, a small fraction of the light 18' radiated from the light source 12 will not pass through the tissue 16 but pass directly to the detector 14, through the small space 18 between the sensor 10 and the tissue 16. Since the detector can not differentiate between the two lights, 14' and 18', the analysis results will be inaccurate.

### SUMMARY OF THE INVENTION

It is an object of the present invention to provide a sensor for radiance based diagnostics of body tissues, which ensures that only light which has passed through an examined tissue is received by the sensor's detector.

5 The sensor is for placing on an examined tissue and comprises a performing component and an adhering component. The performing component, which consists of at least one radiance source for radiating a tissue and at least one detector for detecting the rays transmitted through or reflected from the tissue, protrudes from the plane of the adhering component, in the  
10 direction of the examined tissue, when being placed on the tissue. The adhering component consists of means for fastening the performing component to the examined tissue. The adhering component may be a tape of any suitable adhering material, which forms a frame around the performing component or, the adhering component may be a tape which overlays the performing  
15 component, and which, when being fastened to an examined tissue, covers the performing component, fastening it to the underlying tissue.

The design of the sensor, as described above, ensures that, when the adhering component is placed in contact with the tissue, the performing component presses into the tissue in such a way that the light source and  
20 detector are sealed off from each other by the tissue, thus, when the sensor is operated, only rays from the light source, which have passed through the examined tissue, will be received by the detector.

In one embodiment of the invention, the performing component further comprises a raised partition in between the light source and the  
25 detector, or a wall surrounding either the light source or the detector, or both.

while separating them from each other. The partition or wall assist in sealing off the detector from the light source, to further ensure that no light is received by the detector, directly from the light source.

In another embodiment, the sensor includes a controlling device  
5 which senses external conditions and which is capable of responding to the sensed conditions, such as by arresting the sensor operation when the external conditions indicate inaccurate operation of the sensor. For example, the controlling device may be a pressure or proximity detector that will enable sensor operation only when it senses the required proximity to the examined  
10 tissue or a pressure which indicates that the performing component is sufficiently pressed on to the examined tissue.

It is further an object of the present invention to provide a system for radiance based diagnostics of body tissues. The system comprises a sensor and a microprocessor that is in electronic communication with a component of  
15 the sensor.

The sensor comprises a performing component consisting of at least one radiance source for radiating a tissue and at least one detector for detecting the rays transmitted through or reflected from the tissue, and an adhering component that consists of means for fastening the performing  
20 component to an examined body tissue. The microprocessor is in electronic communication with the performing component of the sensor for controlling the light source and the detector, and for performing analysis of the data received by the detector.

The sensor may also comprise a controlling device that senses  
25 external conditions. The controlling device may be in communication with the

microprocessor, providing information to the microprocessor which contributes to its operation of controlling the light source and detector. Alternatively, the controlling device may be in direct communication with the light source and/or detector, for controlling their operation in accordance with the sensed external

5 conditions.

It is another object of the present invention to provide a method for radiance based analysis of body tissues. The method comprises the steps of fastening the sensor of the invention to an examined tissue, operating the sensor and obtaining data from the sensor.

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**BRIEF DESCRIPTION OF THE FIGURES**

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

9           Fig. 1 is a schematic side view of a prior art sensor;

          Figs. 2A and 2B are schematic under views of the sensor according to two embodiments of the present invention;

          Fig. 2C is a schematic side view of the sensor according to another embodiment of the present invention.

10           Figs. 3A and 3B are schematic side views of the sensors of Figs. 2A and 2B, respectively, operable according to an embodiment of the present invention;

          Figs. 4A and 4B are schematic under views of the sensors of Figs 2A and 2B, respectively, according to another embodiment of the present  
15   invention; and

          Figs. 5A and 5B are block diagram illustrations of the operation of a system including the sensors of Figs. 2A and 2B and the sensor of Fig 2C, correspondingly.

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## DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a sensor for radiance based  
5 diagnostics of body tissues, which ensures that only light from a light source,  
which has passed through an examined tissue, is received by the sensor's  
detector, thereby ensuring higher accuracy of results.

The invention will be described in reference to reflective pulse  
oximetry, but it will be appreciated by persons skilled in the art, that the  
10 invention relates to any radiance based method of diagnosing body tissues,  
reflective or other. The light source and detector, may, therefore, be situated on  
the same side of the examined tissue or on opposing sides, according to the  
diagnostic method used. The terms "light source" and "detector", in the present  
invention, relate to one or more light source or detector. Furthermore, the term  
15 "light source", in the present invention, refers to a radiance source which is not  
limited to visible light but may radiate in any wavelength which is suitable for the  
specific method used.

Reference is now made to Figs. 2A, 2B and 2C, which are schematic  
under views (Fig. 2A and 2B) and side view (Fig. 2C) of a sensor, generally  
20 referenced 20. The sensor 20 comprises a performing component 21 and an  
adhering component 23. The performing component 21 consists of a light  
source 22 for radiating a tissue and detector 24 for detecting the rays reflected  
from the tissue. The whole performing component 21, or parts of it (such as the  
light source 22 and/or detector 24), protrude from the plane of the adhering  
25 component 23.

The adhering component 23 is a tape for fastening the performing component to an examined body tissue, and for keeping it in place. In Figs. 2A and 2C, the adhering component 23 is an adhesive tape forming a frame around the performing component 21. In Fig. 2B the adhering component 23 is a tape, such as of stretchable material, which overlays the performing component, and which, when being fastened to a body tissue, covers the performing component, fastening it to the underlying tissue. The adhering component 23 may be disposable.

The performing component 21 may be powered through a cable 26 (shown only in Fig. 2B). Alternatively, the sensor 20 may be wireless and operated on a battery.

The embodiment described in Fig 2C further comprises a controlling device 126 that may be in communication with either detector 24 or light source 22 or both. Controlling device 126 is capable of sensing external conditions and responding to these conditions. A detailed description of controlling device 126 is provided in Fig. 5B.

Reference is now made to Figs. 3A and 3B which are schematic side view illustrations of a sensor operable according to the invention. When the sensor, generally referenced 30, is placed on a body tissue 35, such that the adhering component 33 is placed in contact with the tissue 35, the performing component 31, which protrudes from the plane of the adhering component 33, in the direction of the tissue 35, presses into the tissue 35, forming indentation 35'. Adhering component 33 is in contact with performing component 31, such that, the adhering component surface 33' is essentially parallel to the performing component surface 31'. Accordingly, when sensor 30 is fastened to

tissue 35, there is essentially no space between the adhering component 33, and the tissue 35. This ensures that the performing component 31 is pressed onto tissue 35 such that light cannot reach the detector either from the outside or directly from the light source.

5           The pressure exerted by performing component 31 on the tissue, fastens the light source and detector (not shown) to the tissue so that rays emitted from the light source, are unable to reach the detector through any other medium, but the tissue.

10           The performing component surface 31' can be coated or overlaid with a soft layer, such as a silicone or sponge layer. The soft layer will contribute to sealing off of the light source from the detector when the sensor is pressed onto the tissue 35.

15           Reference is now made to Figs 4A and 4B which are schematic under view illustrations of a sensor, generally referenced 40, according to another embodiment of the invention. In this embodiment the performing component 41 of the sensor 40 comprises a raised partition 45 in between the light source 42 and the detector 44. The sensor 40 may also comprise a wall 46' surrounding either the light source 42 or the detector 44, or both, while separating them from each other (shown in Fig. 4B). When sensor 40 is fastened to a body tissue (as  
20           described in Figs. 3A and 3B) by adhering component 43, partition 46 or wall 46', which are raised above the plane of the sensor 40, exert pressure on the tissue and thus seal off the detector 44 from the light source 42.

25           Reference is now made to Fig 5A, which is a block diagram illustration of the operation of a system for radiance based diagnostics of body

tissues, which includes the sensors 20 of Figs. 2A and 2B. The system comprises a microprocessor 130 that is in electronic communication with the performing component of sensor 20 which includes light source 132 and detector 134. Microprocessor 130 controls light source 132 and/or detector 134 operation. Detector 134 provides microprocessor 130 with data relating to the light detected by it. Microprocessor 130 performs data analysis 138 which may include saving the data and/or further processing it and, optionally, displaying the processed data. Data analysis 138 may be performed in the same physical unit of microprocessor 130 or in a separate unit which is in communication with microprocessor 130. The processed data may further effect microprocessor 130 operation. Thus the microprocessor 130 operation may be fine tuned in accordance with the conditions prevailing in the examined tissue, as they are interpreted by the data analysis function of the microprocessor.

Fig 5B is a block diagram illustration of a system for radiance based diagnostics of body tissues, that includes the sensor 20 of Fig. 2C. This sensor includes controlling device 136 that may be in communication with microprocessor 130, on one hand and with light source 132 and detector 134, on the other hand, and through which microprocessor 130 may control light source 132 and detector 134 operation.

Controlling device 136 responds to external conditions, such as external pressure or external temperature, and may inform microprocessor 130 of these conditions. Microprocessor 130 may be programmed to differentially operate according to different external conditions. For example, controlling device 136 may function to alert microprocessor 130 of the fact that there is insufficient pressure or proximity to the examined tissue, and according to the

programmed parameters, microprocessor 130 may either stop sensor 20 operation, or alert an operator by displaying this fact, through data analysis 138.

Alternatively, controlling device 136 may be a switch which responds to pressure or proximity to the examined tissue 35 (see Figs. 3a and 3b). Thus, when the performing component 21, or parts of it, are sufficiently pressed to examined tissue 35, so as to ensure that only light from light source 132 that has passed through the examined tissue 35, will be detected by detector 134, the controlling device 136 will be in the ON indication, either enabling microprocessor 130 operation or enabling electronic communication between the microprocessor 130 and light source 132 and detector. When insufficient pressure or proximity, between the performing component and the examined tissue, is detected by controlling device 136, it will be in the OFF indication, thereby either arresting microprocessor 130 operation or disconnecting the electronic communication between the microprocessor 130 and light source 132 and detector 134. Thus the controlling device 136 contributes to the sensor 20 efficiency.

The controlling device 136 may also respond to other external parameters, such as the examined tissue temperature. Thus, the controlling device 136 will either alert an operator, disconnect the microprocessor or disconnect electronic communication between the microprocessor and the performing component, if it senses a temperature different from that of a preprogrammed temperature, such as the body temperature. The sensor 20, which may be placed on the examined tissue 35 for a long period, such as over night, may heedlessly fall off the examined tissue 35 and be pressed on to the patient's bed, instead of onto his body. The microprocessor 130 will be alerted

to this fact by the controlling device 136, and act accordingly, as described above.

The controlling device 136 may additionally function to ensure that the microprocessor 130 is operative only with the appropriate sensor 20. For example, sensor 20 can include a controlling device 136 that is a pressure detector that is in the OFF indication for the time it takes to achieve appropriate pressure between the sensor and the examined tissue. Accordingly, microprocessor 130 can be programmed to operate only after being shut off for a predetermined period (which would be the time it takes to achieve appropriate pressure between the sensor and examined tissue). Thus, a sensor 20 that does not include a controlling device 136 will not be operative with the programmed microprocessor 130.

Both in Fig 5A and in Fig 5B, the microprocessor 130 control of the sensor 20 components (light source 132 and/or detector 134) may be achieved through connecting wires or by remote control, such as by utilizing radiant energy. Thus the microprocessor 130 may be in close contact with the sensor 20, situated close to the patient's body, or the microprocessor 130 may be at some distance from the sensor 20.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

**CLAIMS**

1. A sensor, for radiance based diagnostics, comprising

a performing component and an adhering component

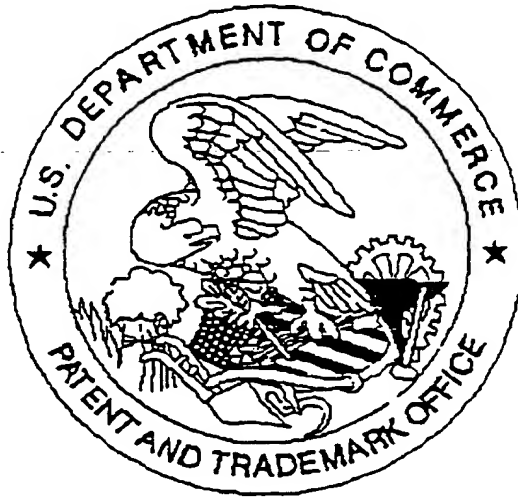
5        said performing component comprising at least one radiance  
source for radiating a tissue and at least one detector for detecting  
rays emitted from said radiance source which are transmitted  
through or reflected from the tissue, and

      said adhering component comprising means for fastening  
the performing component to an examined body tissue.

10       wherein, when operative, the radiance source and detector are  
sealed off from each other.

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Fig. 1

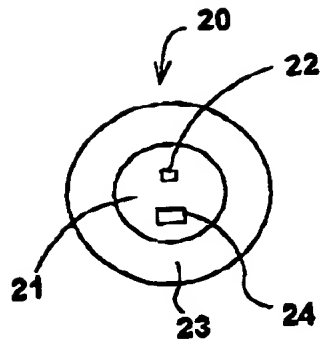
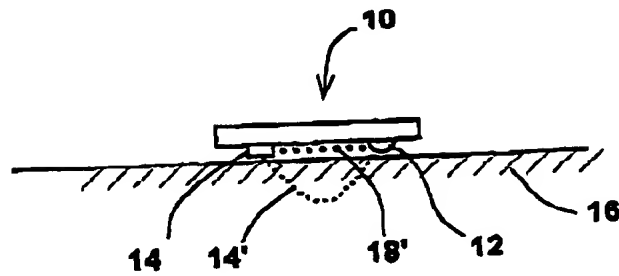


Fig. 2A

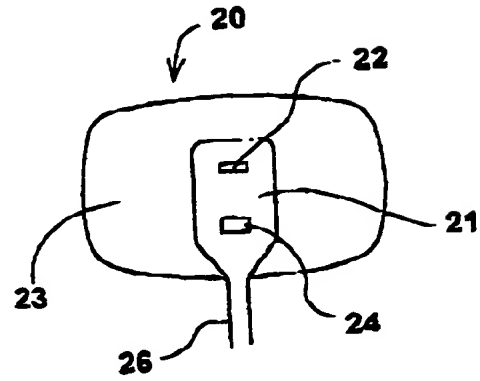


Fig. 2B

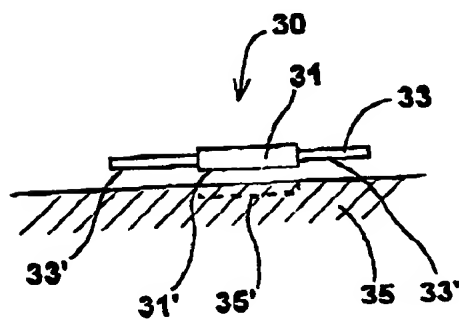


Fig. 3A

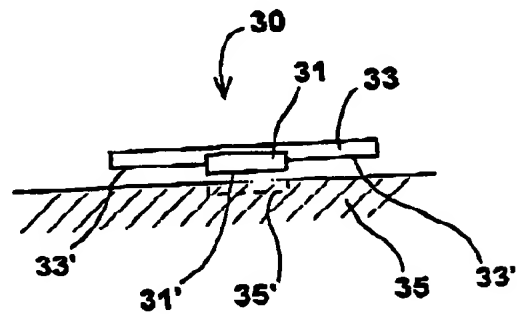


Fig. 3B

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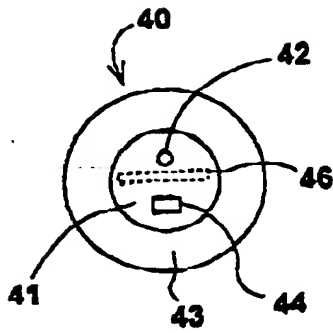


Fig. 4A

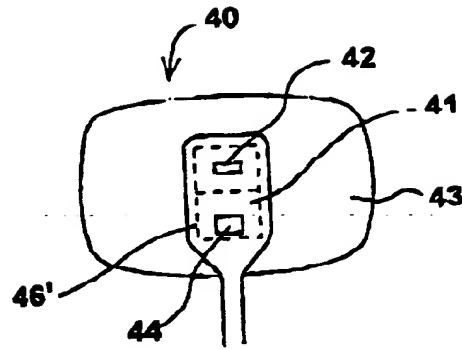


Fig. 4B

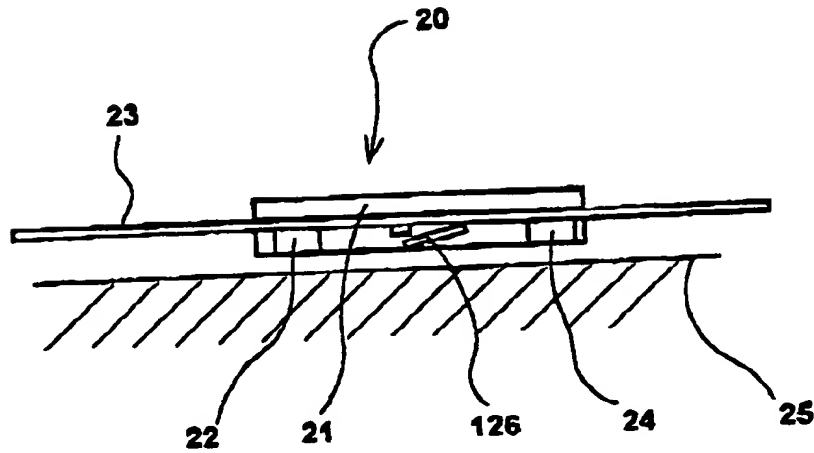


Fig. 2C

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FIG. 5A

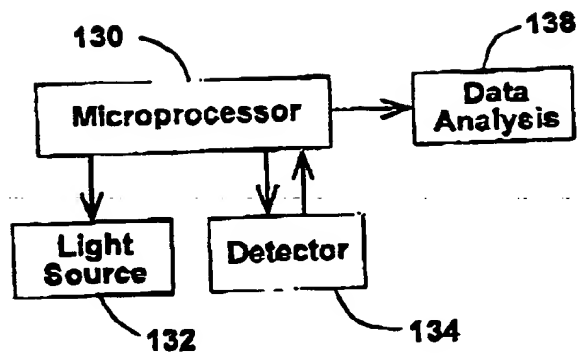
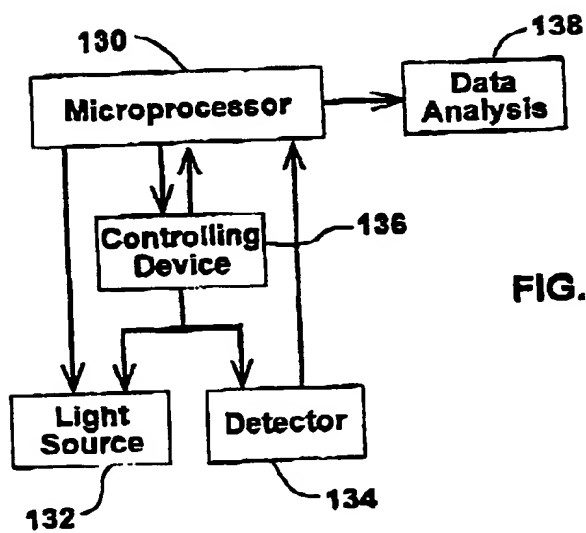


FIG. 5B





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